**CLEARED**

May 25, 2017
27 days to decision

# K171253 Streamline 6491 Unipolar Pediatric Temporary Pacing Lead, Streamline 6492 Unipolar Temporary Pacing Lead, Streamline 6495 Bipolar Temporary Myocardial Pacing Lead, Streamline 6500 Unipolar Temporary Myocardial Pacing Lead

K171253 · Product code: **LDF** · Cardiovascular
Source: https://www.510kdatabase.net/k171253/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Electrode, Pacemaker, Temporary (LDF) |
| Date received | Apr 28, 2017 |
| Decision date | May 25, 2017 |
| Days to decision | 27 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Medtronic** |
| Location | Minneapolis, MN, US |
| Contact | Debra Taitague |
| Website | http://www.medtronic.com/us-en/index.html |
| 510(k) history | 32 submissions · 32 cleared · 2007-2026 |

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...